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Ole Sibbesen

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EXAMINER

RAGHU, GANAPATHIRAM

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/626,583	Applicant(s) SIBBESEN ET AL.	
	Examiner GANAPATHIRAMA RAGHU	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,13,44-47,56-67,69 and 70 is/are pending in the application.
- 4a) Of the above claim(s) 10,13 and 44-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-67,69 and 70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Application Status

In response to the Office Action mailed on 10/12/2007, applicants' filed a response on 04/11/2008. Said response, amended claims 56-59, cancelled claim 68. Claims 10, 13, 44-47, 56-67, 69 and 70 are pending in this application, claims 10, 13 and 44-47 remain withdrawn as they are drawn to non-elected inventions. Claims 56-67, 69 and 70 are now under consideration.

Objections and rejections not reiterated from previous action are hereby withdrawn.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). This application is a CON of 09/869,155 filed on 10/01/2001 ABN, which is 371 of PCT/IB99/02071 filed on 12/17/1999 371 and claims the priority date of United Kingdom application 9828599.2 filed on 12/23/1998, United Kingdom application 9907805.7 filed on 04/06/1999 and United Kingdom application 9908645.6 filed on 04/15/1999. Certified copies of said foreign applications have been provided in the original parent application 09/869,155 filed on 10/01/2001, therefore instant claims get the priority date of 12/23/1998.

Withdrawn- 35 USC § 102

Previous rejection of claims 56 and 58 rejected under 35 U.S.C. 102(b) as being anticipated by Paice et al., (Accession No.: P18429, UniProt Database, 1990 and Arch. Microbiol. 1986, Vol. 144: 201-206 cited in IDS) or Wolf et al.,

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(Accession No.: I40569, PIR database, 1996 and Microbiology, 1995, Vol. 41: 281-290, cited in IDS) is being withdrawn due to amendments to claims.

Previous rejection of claims 57 and 59 rejected under 35 U.S.C. 102(b) as being anticipated by Campbell et al., (U.S. Patent No.: 5,405,769, date of patent 04/11/1995) is being withdrawn due to amendments to claims.

Maintained-Claim Rejections 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 56-66, 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haarasilta et al., (U.S. Patent No.: 5,176,927, date of patent 06/05/1993) or Poutanen K (1997) in view of Paice et al., (Accession No.: P18429, UniProt Database, 1990 and Arch. Microbiol. 1986, Vol. 144: 201-206 cited in IDS) or Wolf et al., (Accession No.: I40569, PIR database, 1996 and Microbiology, 1995, Vol. 41: 281-290, cited in IDS) and Campbell et al., (U.S. Patent No.: 5,405,769, date of patent 04/11/1995).

Haarasilta et al., disclose baking products comprising yeast and use of xylanases in said baking products and methods for determining the softness and stickiness of doughs comprising xylanases and yeast including altering the liquid

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requirement ratio (flour vs liquid). Said reference teaches that: a) it is preferable to use less liquid as it cuts the cost of production of bread by lowering the time required for baking and one of the accepted methods in the baking industry is the addition of cellulolytic and hemicellulolytic enzymes such as xylanase to cleave non-starch polysaccharides present in flour which improves the properties of baking process and the finished baking product; b) as addition of cellulolytic and hemicellulolytic enzymes (xylanases) makes the dough softer, so less dough liquid is required as compared with conventional techniques; and c) the reduced concentration of water requires less energy than prior art methods and in large scale baking processes, this improved efficiency will result in substantial cost savings (columns 2, lines 32-34; column 3, lines 40-66; columns 4-6, column 11, line 37-50).

Poutanen K also teach use of xylanases in baking, baking products and doughs and the mechanism of action of added enzymes in baking products such as improved dough handling properties and specifically: a) effect of addition of xylanases to said baking products resulting in improved product quality (column 2, page 302; column 2, page 303 and Fig. 1); b) addition of xylanase was effective in increasing the specific volume of wheat bread without causing stickiness (Table 3, page 304); c) use of xylanase would cause water redistribution from pentosans to gluten phase, facilitating extensibility and resulting in better oven spring (column 1, page 304); and d) xylanases have been employed to control the viscous and water binding properties in baking products for retaining a tender, non-brittle and shelf-stable structure (column 2, page 304).

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However, Haarasilta et al., or Poutanen K are silent regarding using xylanase in said baking products and said xylanase having the amino acid sequence of SEQ ID NO: 5 and encoded by a polynucleotide sequence of SEQ ID NO: 6 or wherein said xylanase having the amino acid sequence of amino acid residues 29-213 of SEQ ID NO: 5 lacking the leader sequence.

Paice et al., or Wolf et al., teach the isolation of a polynucleotide and encoding polypeptide from a *Bacillus subtilis* strain having 100% sequence homology to SEQ ID NO: 6 of the instant application and the encoded polypeptide has 100% sequence homology to SEQ ID NO: 5 and having xylanase activity.

Similarly, Campbell et al., teach the isolation of a *Bacillus* xylanase having 100% sequence homology to the amino acid sequence of amino acid residues 29-213 of SEQ ID NO: 5 lacking the leader sequence (SEQ ID NO: 37; columns 219 and 220) and also suggest the use of said xylanase for altering the texture in bakery products (column 1).

It would have been obvious to a person of ordinary skill in the art to use the xylanases of Paice et al., or Wolf et al., and Campbell et al., in baking, baking products and doughs as suggested by Haarasilta et al., or Poutanen K. Motivation to do so derives from the fact that addition of xylanases to said baking products results in improved product quality and specifically mention that addition of xylanase was effective in increasing the specific volume of wheat bread without causing stickiness. The expectation of success is high, because Paice et

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al., or Wolf et al., and Campbell et al., teach the isolation of xylanases including xylanases lacking the leader sequence with desirable properties and having 100% sequence homology to SEQ ID NO: 5 of the instant application and Haarasilta et al., or Poutanen K disclose the advantages of addition of xylanases in baking, baking products and doughs. Therefore, claims 56-66 and 68-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haarasilta et al., (U.S. Patent No.: 5,176,927, date of patent 06/05/1993) or Poutanen K (1997) in view of Paice et al., (Accession No.: P18429, UniProt Database, 1990 and Arch. Microbiol. 1986, Vol. 144: 201-206 cited in IDS) or Wolf et al., (Accession No.: I40569, PIR database, 1996 and Microbiology, 1995, Vol. 41: 281-290, cited in IDS) and Campbell et al., (U.S. Patent No.: 5,405,769, date of patent 04/11/1995).

Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haarasilta et al., (U.S. Patent No.: 5,176,927, date of patent 06/05/1993) or Poutanen K (1997), Paice et al., (1986) or Wolf et al., (Accession No.: I40569, PIR database, 1996 and Microbiology, 1995, Vol. 41: 281-290, cited in IDS), Campbell et al., (U.S. Patent No.: 5,405,769, date of patent 04/11/1995) and further in view of Autio et al., (Academic Press, 1996, pages 18-27).

The combination of Haarasilta et al., or Poutanen K, Paice et al., or Wolf et al., and Campbell et al., is described above. Although, said combination teaches the isolation and addition of purified xylanase to bakery products, doughs and in baking, said combination does not explicitly teach xylanase free of glucanase enzymes. Autio et al., teach the effects of purified xylanase and glucanase on the

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structural and baking characteristics of doughs, said reference discloses that addition of glucanase had a hardening effect on doughs and bakery products (column 1, page 21 and Table 3, page 22). It would have been obvious to a person of ordinary skill in the art to combine the teachings of Haarasilta et al., or Poutanen K, Paice et al., or Wolf et al., Campbell et al., and Autio et al., to adopt the enzymatic reaction conditions for baking products and doughs comprising the xylanase enzyme to be devoid of glucanase as presence of glucanases catalyzes the breakdown of substrates that results in unwanted hardening effect on said products. Therefore, Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haarasilta et al., (U.S. Patent No.: 5,176,927, date of patent 06/05/1993) or Poutanen K (1997), Paice et al., (1986) or Wolf et al., (Accession No.: I40569, PIR database, 1996 and Microbiology, 1995, Vol. 41: 281-290, cited in IDS) and Campbell et al., (U.S. Patent No.: 5,405,769, date of patent 04/11/1995) and further in view of Autio et al., (Academic Press, 1996, pages 18-27).

Therefore, the above references render claims 56-67, 69 and 70 *prima facie* obvious to one of ordinary skill in the art.

In support of their request that the prior rejection of claims 56-67, 69 and 70 under 35 U.S.C. 103(a) be withdrawn, applicants' provide the following arguments. These arguments are relevant to the new rejection explained above.

(A) The Supreme court...requires that the reasoning used to combine the elements in the fashion claimed be made explicit.

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(B) Haarasilta relates to improving the production of cereal production of cereal products in adding hemi-cellulose or cellulose degrading enzymes. Haarasilta does not teach or suggest a bacterial xylanase which is expressed from the nucleotide sequence of SEQ ID NO: 6.

(C) Campbell is directed to a "modified xylanase, which shows an improved thermostability when compared to the naturally occurring xylanase"... Examiner does not specifically indicate which sequence of Campbell is 100% identical to amino acids 29-213 of SEQ ID NO: 5, however, there is nothing in Campbell to suggest that a protein having the amino acid sequence of can be used in a bakery product or dough for a bakery product and the examiner points to a vague statement in the background of Campbell and attempts to combine that with the alleged disclosure.

(D) Poutanen is a review of enzymes used to improve the quality of cereals. Poutanen discusses that the use of xylanases may increase viscosity, increase bread volume and decrease staling in bread and references such as Maat cited by Poutanen actually teach away from the use of bacterial xylanases in bakery products or doughs.

Reply (A), (B), (C) and (D): Applicants' arguments have been considered but are found to be non-persuasive for the following reasons:

Applicant's arguments are directed against the references individually. However, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091,

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231 USPQ 375 (Fed. Cir. 1986).

The cited references are in congruence with the obviousness rejection and teach all limitations of the instant claims i. e., meet all the criteria and parameters (Teaching, Suggestion and Motivation) as defined by *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) and the rationale for TSM test (Teaching, Suggestion and Motivation) according to KSR ruling.

Moreover, the objectives of the cited references need not be the same as the instant invention to be used in an Obviousness rejection. So long as the motivation or suggestion to combine the teaching of the cited references is known or disclosed in the prior art and is obvious to one skilled in the art. This is sufficient to establish a *prima facie* case of obviousness.

Examiner would like to reiterate the significant teachings of the cited prior on which the rejection is based.

(1) Paice et al., teaches that xylanases differ in their activities i.e., the xylanase isolated by Paice et al., that has 100% sequence homology to SEQ ID NO: 5 of the instant application is an endoxylanase and the primary activity of the cloned enzyme is hydrolysis of xylans and not cellulose (column 1, page 204 and entire document).

(2) Campbell et al., teach the isolation of a *Bacillus* xylanase having 100% sequence homology to the amino acid sequence of amino acid residues 29-213 of SEQ ID NO: 5 lacking the leader sequence (SEQ ID NO: 37; columns 219 and 220) and also suggest the use of said xylanase for altering the texture in bakery products (column 1).

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(3) Haarasilta et al., teaches that xylanase activity represents hemicellulolytic activity (column 5, lines 36-39).

Therefore, the references of Paice et al., Wolf et al., Campbell et al., and Haarasilta et al., teach the structural and functional elements of the instant invention a xylanase, with specifically an endoxylanase and the primary activity of the cloned enzyme is hydrolysis of xylans.

(4) Poutanen K teaches that in an attempt to understand the sequential reactions such as effect of enzymes on doughs and baking products in altering the molecular properties, microstructure, functional properties and product quality, several reports are directed to studying the mechanism of action of xylanases. Xylanases release high molecular weight water-soluble arabino-xylans from water-unextractable cell wall material. The specific viscosities of extracts from xylanase-treated doughs were 40-65% higher than those extracts from untreated dough, because the average apparent viscosity of the extracted arabino-xylans remained high. Thus it becomes clear to one of skill in the art that xylanases with desirable specific activities determine the effect of enzymes on doughs and baking products in altering the molecular properties, microstructure, functional properties and product quality and a skilled artisan would employ a xylanase with the desired activity.

5) Specifically regarding the argument "References such as Maat cited by Poutanen actually teach away from the use of bacterial xylanases in bakery products or doughs", examiner would like to state that said reference was never cited by the examiner in the rejection and the applicants use of the reference in

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the argument is not relevant to the basis of rejection adopted by the examiner, as examiner has provided the reason for the use of xylanase isolated by Paice et al., Wolf et al., Campbell et al., and Haarasilta et al., that teach the structural and functional elements of the instant invention and having the desired activity.

Therefore, the examiner continues to hold the position that the combination of the cited references renders the instant invention obvious for the following reasons. One of ordinary skill in the art would have been motivated to employ the bacterial xylanase taught by Paice et al., or Wolf et al., Campbell et al., and Haarasilta et al., for making a bakery product or a dough comprising the polypeptide having the desirable xylanase activity i.e., endoxylanase for the hydrolysis of xylans present in the ingredients such as flour in a bakery product. One of ordinary skill in the art would have been motivated to combine these references because Poutanen K clearly suggests that: in an attempt to understand the sequential reactions such as effect of enzymes on doughs and baking products in altering the molecular properties, microstructure, functional properties and product quality, several reports are directed to studying the mechanism of action of xylanases. Poutanen K also suggest that xylanases release high molecular weight water-soluble arabino-xylans from water-unextractable cell wall material and thus a skilled artisan would certainly be interested to understand the effect of the xylanase isolated by Paice et al., or Wolf et al., or Campbell et al., on a bakery product or a dough, i.e., its mechanism of action and would be motivated to employ the xylanase isolated by Paice et al., or Wolf et al., and Campbell et al. One of ordinary skill in the art

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would have a reasonable expectation of success because use of xylanases in a bakery product or a dough were known in the prior art: (1) Haarasilta et al., disclose baking products comprising yeast and use of xylanases in said baking products and methods for determining the softness and stickiness of doughs comprising xylanases and yeast including altering the liquid requirement ratio (flour vs liquid) and (2) Poutanen K also teach use of xylanases in baking, baking products and doughs and the mechanism of action of added enzymes in baking products such as improved dough handling properties and specifically: a) effect of addition of xylanases to said baking products resulting in improved product quality (column 2, page 302; column 2, page 303 and Fig. 1); b) addition of xylanase was effective in increasing the specific volume of wheat bread without causing stickiness (Table 3, page 304); c) use of xylanase would cause water redistribution from pentosans to gluten phase, facilitating extensibility and resulting in better oven spring (column 1, page 304); and d) xylanases have been employed to control the viscous and water binding properties in baking products for retaining a tender, non-brittle and shelf-stable structure (column 2, page 304).

The basis for the examiner to continue to hold his position is reasoned below; examiner has provided unequivocal evidence for combining the cited references and that the cited references have been properly applied in this obviousness rejection in accordance with the factual enquires set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) and the rationale for TSM test (Teaching, Suggestion and Motivation) according to KSR ruling. Furthermore the cited references teach all the limitations of the instant claims.

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The cited references render claims 56-67, 69 and 70 *prima facie* obvious to one of ordinary skill in the art when one applies the Teaching, Suggestion and Motivation (TSM) test under the rationale for arriving at a conclusion of obviousness as suggested by the KSR ruling. The rationale applied for this rejection is as follows:

- (1) Combining prior art elements according to known method to yield predictable results.
- (2) Simple substitution of one known element for another to obtain predictable results.
- (3) "Obvious to try"- choosing from a finite number of identified, predictable solution, with a reasonable expectation of success.

The instant invention is a simple combination of elements taught in the prior art, wherein the elements of prior art are combined to yield predictable results and the choice is from a finite number of identified elements with a highly predictable outcome and expectation of success.

Examiner would like to point out that the arguments presented above are based on Graham factual enquires:

- (1) a finding that at the time of the invention, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem; The need here is use of novel xylanases with desirable properties for use in the a bakery product or dough and to identify xylanases to achieve reactions that yield the optimal alteration in the molecular properties, microstructure, functional properties and product quality.

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(2) a finding that there had been a finite number of identified, predictable potential solutions to the recognized need or problem; Knowledge of use of xylanases in the baking industry is well known in the art.

(3) a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success; and therefore there is clear motivation for commercial exploitation; as discussed above, Paice et al., Wolf et al., Campbell et al., and Haarasilta et al., teach the structural and functional elements of the instant invention i.e. an enzyme with endo-xylanase activity.

The arguments set forth above demonstrate that the instant claims are *prima facie* obvious in that “one of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense.” Therefore, one of ordinary skill in art would have found it obvious to combine the teachings of Haarasilta et al., (U.S. Patent No.: 5,176,927, date of patent 06/05/1993) or Poutanen K (1997), Paice et al., (1986) or Wolf et al., (Accession No.: I40569, PIR database, 1996 and Microbiology, 1995, Vol. 41: 281-290, cited in IDS), Campbell et al., (U.S. Patent No.: 5,405,769, date of patent 04/11/1995) and Autio et al., (Academic Press, 1996, pages 18-27).

Summary of Pending Issues

The following is a summary of issues pending in the instant application.

Claims 56-67, 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haarasilta et al., (U.S. Patent No.: 5,176,927, date of patent

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06/05/1993) or Poutanen K (1997), Paice et al., (1986) or Wolf et al., (Accession No.: I40569, PIR database, 1996 and Microbiology, 1995, Vol. 41: 281-290, cited in IDS), Campbell et al., (U.S. Patent No.: 5,405,769, date of patent 04/11/1995) and Autio et al., (Academic Press, 1996, pages 18-27).

Conclusion

None of the claims are allowable. Claims 56-67, 69 and 70 are rejected for the reasons identified in the Rejections and Summary sections of this Office Action. Applicants must respond to the objections/rejections in each of the sections in this Office Action to be fully responsive for prosecution.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached between 8 am-4: 30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.
Patent Examiner
Art Unit 1652
July 21, 2008.

/Rebecca E. Prouty/
Primary Examiner,
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